K061530

JUL 21 2006

XI. **510 (k) SUMMARY**

Submitter: Mr. T. H. Kim, BioQM Manager, Meta Biomed Co., Ltd., Cheongju City, Chungbuk, Korea. Tel: 82-43-218-1983.

I. Classification Names and Numbers: Temporary Crown and Bridge Resins were classified by the Dental Panel in CFR 872.3770, Code EBG, Class II.

II. Common/Usual Name: Temporary Dental Restorative: Temporary Filling Material.

III. Proprietary Names: MD-Temp™

IV. Establishment Registration Number: Foreign, in process

V. Performance Standard: None established under section 514. However, material meets ISO 10993 For biocompatibility.

VI. Device Description: MD-Temp™ is a temporary resin for formation of temporary fillings, and other temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated. It is a hydraulic temporary restorative. The formula for MD-Temp™ is listed in Attachment I. It is available in white (tooth-like) or pink (gum-like) colors in small jars (e.g. 40 gm.) jars, individually boxed. It is intended primarily as a temporary filling material for most cavities or damages but may be used by the dentist for other temporary restorations.

VII. Labels and Labeling: Draft labels of MD-Temp™ and instructions for use are provided.

VIII. Indications for Use: For fabrication of temporary fillings and other temporary prosthetics for use until the permanent prosthetic is ready for installation.
Intended to restore carious lesions or structural defects in teeth temporarily. Intended for use in cavities Classes I, II, III, IV (inlays and onlays) and as a restorative material for veneers, crowns and bridges.

IX. Substantial Equivalence: MD-Temp™ is substantially equivalent to several temporary resins for tooth restoration currently on the market. These include (among others): "Protemp 3 Garant," K033022; "Acrylic," K024282; "Protemp H," K002364; "Hydro-Cast Bis-Acryl Temporary Crown and Bridge Material," K001309 and "Cavit-W," K875133. Physical properties, compositions, and use of MD-Temp™ are similar to predicate 510(k)s. The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tae-Hoon Kim
BioQM Manager
Meta Biomed Company, Ltd.
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Cheongju City, Chunbuck 361-140
REPUBLIC OF KOREA

JUL 21 2006

Re: K061530
Trade/Device Name: MD-Temp™
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: May 15, 2006
Received: June 05, 2006

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

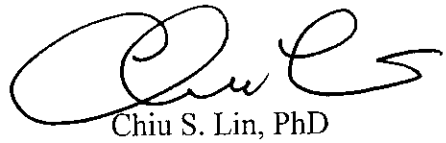
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**VIII. Indications for Use: [Separate Page]**

**510(k) Number:** K061530

**Device Name:** MD-Temp™

**Indications for use:**

For fabrication of temporary fillings and other temporary prosthetics for use until the permanent prosthetic is ready for installation.
Intended to restore carious lesions or structural defects in teeth temporarily. Intended for use in cavities Classes I, II, III, IV (inlays and onlays) and as a restorative material for veneers, crowns and bridges.

Prescription Use__X___ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use_____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Robert S Betz DDS for Dr. Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K061530